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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,772	11/06/2002	Noritsugu Yamasaki	06501-065001	5741

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EXAMINER	
WRIGHT, SONYA N	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/647,772	YAMASAKI ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 1-4 is/are allowed.

6)☒ Claim(s) 5-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1-28-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment filed January 28, 2004. Claims 1-7 have been amended. Claims 8 and 9 have been added. Claims 1-9 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7)Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

Claim 8 is drawn to a method for preventing or treating impaired glucose tolerance, diabetes, diabetic complications etc. . . Claim 9 is drawn to a method for lowering blood sugar levels.

2) State of the prior art.

Applicants disclose that the instant compound is useful in treating various diseases. See page 1, lines 17-34, and page 2, lines 1-8. The prior arts do not instant that the instant compound is useful in treating all forms of diseases in claim 8, or all forms of diseases related to the lowering of blood sugar levels.

3) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the instant compound for preventing or treating impaired glucose tolerance, diabetes, diabetic complications, etc. . .and for lowering blood sugar levels.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

4) Level of predictability in the art.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of preventing or treating all forms of impaired glucose tolerance, diabetes, diabetic complications, etc. . . and for lowering blood sugar levels to treat any disease related to blood sugar levels by the instant compound, one of skill in the art is unable to fully predict possible results from the administration of the instant compound due to the unpredictability of the art pertaining to impaired glucose tolerance, diabetes, diabetic complications, etc. . . and lowering blood sugar levels.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art

would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

5) Amount of direction and guidance provided by the inventor.

The specification provides little guidance regarding the use of the instant compound in preventing or treating impaired glucose tolerance, diabetes, diabetic complications etc. . . and for lowering blood sugar levels. Applicant provides information on pag 49, lines 23-35, page 50 in its entirety, and page 51, lines 1-8.

Applicant does not provide evidence that the instant compound is useful in preventing or treating all forms of impaired glucose tolerance, diabetes, diabetic complications etc. . . Applicant has not indicated in claim 9 what diseases are treated by the lowering of blood sugar levels by the instant compound. The guidance is limited because various diseases related to impaired glucose tolerance, diabetes, diabetic complications etc. . . and lowering blood sugar levels have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol.

6) Existence of working examples.

The specification provides one test example on page 49, lines 23-35, page 50 in its entirety, and page51, lines 1-8. However, the test example does not support that the instant compound is useful in treating all forms of impaired glucose tolerance, diabetes, diabetic complications etc. . ., or for lowering blood sugar levels to treat all diseases related to levels of blood sugar.

7) Breadth of claims.

Claims 8 and 9 are extremely broad due to the large number of diseases related to impaired glucose tolerance, diabetes, diabetic complications, etc. . . and to the lowering of blood sugar levels. Applicant has not shown support that the instant compound is useful in treating all forms of diseases related to impaired glucose tolerance, diabetes, diabetic complications, etc. . . and to the lowering of blood sugar levels to treat all diseases related to blood sugar levels.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test how the instant compound is useful in treating all diseases related to impaired glucose tolerance, diabetes, diabetic complications, etc. . . and to the lowering of blood sugar levels to treat all diseases related to blood sugar levels, with no assurance of success.

These rejections can be overcome by Applicant deleting "preventing" from claim 8, and limiting claim 8 to diseases which are supported in the specification with biological data. It is suggested that Applicant limit claim 9 to diseases which are treated by the lowering of blood sugar levels. Any diseases which are listed in claim 9 should be supported in the specification with biological data.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7 refer to an "aldehyde corresponding to R1" in step (a). The phrase "aldehyde corresponding to R1" is unclear. Based on the definition of R1 in claim 1, one cannot determine the metes and bounds of an "aldehyde corresponding to R1". It is unclear what moieties in R1 can contain aldehydes and where aldehyde groups may appear in each moiety. For example, if R1 is an aryl lower alkyl group, it is not clear whether the aldehyde would appear on the aryl or on the lower alkyl group.

Claim Objections

Claim 7 is objected to because of the following informalities: In claim 7, page 8, step (i) there are two question marks (??) after "ammonia". It is suggested that Applicant delete said question marks. Appropriate correction is required.

Allowable Subject Matter

Claims 1-4 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed January 28, 2004 have been fully considered. Applicant's amendments have overcome the rejection of claim 4 under 35 U.S.C. 112, the objection to composition claim 4, and the claim objections for non-elected subject matter. However, Applicant's amendments are not persuasive with respect to the

objection to claims 5-7 for the phrase "aldehyde corresponding to R1". Applicant argues that one of skill in the art reading Applicant's specification would understand the phrase "aldehyde corresponding to R1" in claims 5-7 to mean a compound having the same carbon content and connectivity as R1, but with an aldehyde group at the position corresponding to the point of attachment of R1 to the indole ring. However, it is unclear what moieties in R1 can contain aldehydes and where aldehyde groups may appear in each moiety. For example, if R1 is an aryl lower alkyl group, it is not clear whether the aldehyde would appear on the aryl group or on the lower alkyl group. If an aldehyde appears on said aryl or lower alkyl group, it is not clear what position of the aryl or lower alkyl group would contain the aldehyde. In view of Applicant's amendment to claims 5-7, the rejection under 112 second supra, has been made.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (571) 272-0711. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The Official fax phone number for this Group is (703) 872-9306.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to Technology Center 1600 at (571) 272-1600.

for Joseph K. McKane

Supervisory Patent Examiner

Group 1600

RITA DESAI
PRIMARY EXAMINER

Sonya Wright

April 14, 2004